



PATENT

CO

5/26/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :

Peter Colin Weston BURT :

Serial Number: 09/379,492 :

Group Art Unit: 3754

Filed: August 23, 1999 :

Examiner: Derakshani

For: Aerosol Dispenser With Ultrasonically Welded Closure and Method of Making

BRIEF ON APPEAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This brief on appeal is submitted in triplicate with the required appeal fee. In addition, a petition for a one month extension of time for filing the appeal brief is submitted herewith, along with the required fee, extending the period for filing the brief to May 23, 2000. The brief has been timely filed.

I. REAL PARTY IN INTEREST

The real party in interest is the Assignee of record, Glaxo Group Limited.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences with respect to the claimed invention which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal known to appellant, appellant's legal representative or assignee.

III. STATUS OF THE CLAIMS

This application contains 36 claims. Claims 1-19 have been canceled from the application and are no longer pending.

Claims 20-36 are pending and are the claims on appeal. Claims 20-36 stand finally rejected.

IV. STATUS OF AMENDMENTS AFTER FINAL REJECTION

The amendment after final rejection has been entered.

V. SUMMARY OF INVENTION

The present invention (though not exclusively) is concerned with metered dose medicament aerosols, for example, metered dose inhalers, (page 1, lines 1-5). Such inhalers are used in inhalation therapy for asthmatic patients and the like. Thus, the metered dose is administered into the lungs of the patient, and it is imperative that the material being metered is not contaminated by gasket material (page 1, lines 25-28) and there is minimum leakage (page 2, lines 1-4) and moisture ingress (page 4, line 2).

The present invention provides an aerosol dispenser which comprises a body, a closure sealed to the body and means for dispensing material from the interior of the dispenser, wherein the closure is welded to the body by a metal-to-metal weld. Preferably the welding is carried out ultrasonically; page 2, lines 7-11.

Also included is a method of assembling an aerosol dispenser comprising a metal body, a metal closure, and means for dispensing material from the interior of the dispenser, wherein the closure is welded to the body by a metal-to-metal seal; page 2, lines 12-15. This method includes avoiding exposing the weld joint to a peel force; page 7, lines 3-7:

VI. ISSUES

The first issue on appeal is whether or not claims 20-35 claim the identical invention as that of claims 20-30 and 32-38 of co-pending application serial number 09/149,858 which issued as United States Patent 6,032,835 on March 7, 2000.

The second issue on appeal is whether the rejection of claims 20-35 under the judicially created doctrine of obviousness-type double patenting over claims 20-30 and 32-38 of co-pending application serial number 09/149,858 should be maintained in view of the timely filing of a Terminal Disclaimer and payment of the required fee. The Terminal Disclaimer was filed with the amendment filed after final rejection which was entered on the filing of the Notice of Appeal.

The third issue on appeal is whether the combination of references relied upon in the Final Rejection renders the rejected claims *prima facie* obvious under 35 U.S.C. 103(a).

VII. GROUPING OF THE CLAIMS

The claims as grouped in the Final Rejection do not stand or fall together.

VIII. ARGUMENT

THE FIRST ISSUE ON APPEAL

The Rejection under 35 USC 101 is untenable and should be reversed because the same invention is not being claimed twice.

As stated in MPEP §804, under the heading, Statutory Double Patenting - 35 U.S.C. 101, same invention means identical subject matter.

This section of the manual goes on to state that a reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. That is, is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

Turning to the claims in the '835 patent, claim 1 is the only independent claim in the patent. Claim 1 is directed to a method of assembling an aerosol dispenser comprising a metal body, a metal closure and means for dispensing material from the interior of the dispenser, wherein the closure comprises an annular flange extending circumferentially about its axis, is positioned at the open end and coaxially with the body which comprises a complementary annular flange extending circumferentially about its axis, such as the flanges are parallel and in contact with each other when the flanges are outwardly directed and flat and wherein a fixed member is placed on one side of the pair of flanges and a welding horn in the form of a ring is brought into contact with the other flange to urge the flanges together, said ring being coaxially with and of substantially the same diameter of said flanges, and whereby the ring is vibrated at an ultrasonic frequency about its axis of rotational symmetry to weld the flanges together ultrasonically to form a metal to metal seal.

There is no such limitation in any of the claims on appeal. The claims on appeal do not require the welding horn in the form of a ring to be brought into contact with the flange as required by claim 1 of the '835 patent. The claims on appeal are broader in the same sense as halogen is to chlorine which is discussed in the above noted section of the MPEP. Therefore, the same invention is not being claimed twice since the claims on appeal could be infringed and claim 1 of the patent would not be infringed with a welding horn in the form of a ring. This limitation is not required for infringement of the claims on appeal.

Appellant most respectfully submits that this rejection should be reversed as identical subject matter is not being claimed in the claims on appeal and in the '835 patent. It is only when the same invention is being claimed twice that 35 U.S.C. 101 is applicable.

THE SECOND ISSUE ON APPEAL

The Obviousness-type Double Patenting Rejection Should be Reversed in view of the timely filing of a terminal Disclaimer.

The rejection of claims 20-35 under the judicially created doctrine of obviousness-type double patenting over claims 20-30 and 32-38 of co-pending application serial number 09/149,858 should also be reversed in view of the timely filing of a Terminal Disclaimer and appropriate fee. The final rejection states that the rejection would be withdrawn if a terminal disclaimer was filed. If the rejection is not withdrawn, further explanation of the rejection should be provided in the Examiner's Answer so that this issue may be further briefed. It is believed that the filing of the Terminal Disclaimer has obviated this rejection.

THE THIRD ISSUE ON APPEAL

The rejections over the prior art should be reversed since the combination of references do not render prima facie the claimed subject matter.

Basic Requirements of a Prima Facies Case of Obviousness

The appellant believes that the criteria set forth in the MPEP provides guidance in determining the issue of obviousness of the claims on appeal.

---SECTION---2143 Basic Requirements of a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the

reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

SECTION--2143.03 All Claim Limitations Must Be Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Appellant also most respectfully directs the Examiner's attention to MPEP § 2144.08 (page 2100-130) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

A. The First Criteria of a Prima Facie Case has not been Met

Claims 20-21, 23, 25, 27-29, 31 and 33-35 are rejected under 35 U.S.C. 103 as being unpatentable over Beard et al. in view of Welter. This rejection should be reversed because there is no motivation to combine the references.

None of the prior art relied upon in this rejection in any way recognizes the problem solved by the present invention, let alone the solution. For example, the primary reference (Beard et al.), at column 3, line 25, specifies that the perimeter

regions 3 of the cup 11 are connected to the lip region of the mouth 2 of the container 12 by crimping in the conventional manner well known to the aerosol container field. This is the only portion of the patent which describes the closure of the cup region to the mouth. Thus, there is no suggestion in the primary reference of the ultrasonic metal to metal weld sealed in accordance with the claims on appeal. This is because there was no recognition of the need to improve the seal between the perimeter regions 3 of the cup and the lip region of the mouth. This recognition by Appellant forms part of the invention as a whole and must be taken into consideration in evaluating the patentability of the claims on appeal over the prior art.

The cup of Beard et al has a polypropylene laminate film secured on its entire interior surface portions. This film is therefore also available to aid in forming a seal between the perimeter portions 3 of the cup 11 and the mouth of the container 12 and acts to seal the cup and mouth; see col. 3, lines 57-62 of the patent. This is not a metal to metal weld as required by the claims on appeal. It would appear that this film would be a material which might serve to contaminate the aerosol formulation contained in the aerosols of the present invention in a similar manner to the gasket material which is avoid by the metal to metal weld of the claims on appeal.

The polypropylene laminate of cup 11 is also required to provide a bonding surface to attach thermoplastic olefin vessel 13, which holds valve 18 in place; col. 3, lines 41-55; lines 62-66 of the Beard reference. Beard states that the olefin vessel and laminated cup are joined via ultrasonic welding, however, there is no indication that ultrasonic welding is suitable to join the crimped polypropylene laminated cup and the mouth. Moreover, the Beard reference would apparently teach away from a metal-to-metal ultrasonic weld of the cup and the mouth, as without the polypropylene laminate there would be no mounting surface on the cup to attach vessel 13 within the device. Hence, Beard provides a very strong disincentive to modify the depicted canister in such a way as to provide the metal-to-metal weld recited in the claims now under appeal, and can be viewed to actually teach away from this approach. This is because if such an approach were adopted, it would

require eliminating the laminate surface of the cup and this modification would result in an inoperative device. In such cases, there is no motivation to make the proposed modification as stated in MPEP section 2143.01 (page 2100-112) which cites *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). X

Aerosol dispensers of the type having a closure member crimped to the body with an intermediary seal or gasket function in a largely satisfactory manner, as witnessed by over 30 years of substantially unchanged design and the prior art of record. Nonetheless, as discussed on pages 1 and 2 of the application on appeal, there are problems (discovered by Appellant) associated with conventionally crimped aerosol dispensers including the leaching of substances from the gasket into the material contained within the dispenser, leakage of material out of and ingress of moisture into the dispenser past the gasket, and the additional manufacturing and assembly expenses associated with the requirement for an additional component (gasket) in the dispenser.

However, whether due to complacency or a lack of recognition of these problems, to Appellant's knowledge it has never been suggested that the conventional crimped connection between closure and body might advantageously be replaced by any form of a metal to metal weld which would eliminate the gasket and its associated problems. While Appellant does not dispute the fact that ultrasonic welding techniques have been known for many years, as evidenced for example by Welter, (cited by Appellant on page 3 of the specification) there has never been any indication that ultrasonic welding might be used in the assembly of aerosol dispensers to solve the problems presented by conventional crimped seals of the closure to the body of the aerosol container. Despite the widespread application of metal to metal welding techniques, including ultrasonic welding, the advantages of employing a metal to metal weld, and in particular the specific advantages of ultrasonic welding, have never previously been recognized or employed in the field of aerosol dispensers.

Starting from the aerosol dispenser taught by Beard et al., in the absence of the perception of any advantages to be gained by using an ultrasonic weld and

without the benefit of hindsight, there is no reason why the person skilled in the art of aerosol dispensers would replace the crimped closure/body connection with an ultrasonic weld. Yet Appellant has found this concept to offer significant advantages in the aerosol dispenser manufacturing and assembly process over conventional practice, and it is believed that this advance could potentially revolutionize aerosol dispenser design.

Apart from allowing elimination of the gasket and the associated advantages that this offers as discussed above, ultrasonic welding produces only very localized heating in the region of the weld itself, which enables the can to be filled before the closure is secured thereto since it reduces the risk of the substance to be dispensed being undesirably heated (see page 3, lines 13 to 17). This would not be possible with other heat intensive welding techniques.

The method of ultrasonic welding does not require special preparation of the surfaces to be welded and each closure can be welded to a container very quickly in a single compression stroke using the apparatus depicted in Figure 4 (1/4 second per dispenser) which leads to an efficient manufacturing process.

The ultrasonic weld so produced is strong and results in enhanced performance of aerosol dispensers with regard to leakage and moisture ingress over conventional crimped dispensers (see page 4, lines 1 to 22 together with the test results presented in Tables 1 and 2 and Figures 5 and 6).

The secondary reference to Welter relates to a variable weighted ultrasonic welding horn which may be used for several purposes, including the joining of metals or plastics. It further teaches that ultrasonic welding is often used in applications where high temperatures would be impractical, such as in connecting fine wires to microchips, sealing plastic bags and hermetically closing toothpaste or similar tubes. There is absolutely no suggestion of using ultrasonic welding for sealing aerosol dispensers to form a metal to metal weld as required by the claims on appeal. There must be some teaching in the references of record which lead one of ordinary skill in the art to combine the references to arrive at appellants' claimed invention. Appellants' disclosure may not be used as a teaching reference to

combine the references in the rejection. Clearly, in the present case, in view of the absence of any disclosure suggesting the application of ultrasound welding technique to aerosol dispensers, the rejection is untenable.

B. Appellant does not Contest the Second Criteria

Without making any admission concerning the second criteria, Appellant will not submit any argument on these criteria.

C. The Third Criteria has not been Met

The prior art relied upon in the rejection does not teach all of the limitations of the claims on appeal. This is especially true with respect to claims 25, 28, 30, and 33-35 which do not stand with claims 20, 21 and 23.

For example, there is no disclosure in the Beard et al reference that one of the flanges is of greater width than the other, and wherein the outer edge portion of the wider flange forms a U within which the outer edge portion of the narrower flange is located, both said edge portions extending generally parallel to the adjacent wall of the body as required by claim 25.

There is also no teaching wherein the closure, which comprises an annular flange extending circumferentially about its axis, is positioned at the open end of and coaxially with the body, which comprises a complementary annular flange extending circumferentially about its axis, such that the flanges are parallel and in contact with each other when ultrasonic welded as required by claim 28.

Finally, claim 35 requires that one of the flanges is of greater width than the other and after the flanges have been welded together the wider flange is rolled and crimped around the other flange. These limitations are not shown or suggested by the prior art relied upon in the rejection. These limitations further distinguish over the prior art and provide further advantages by increasing the strength of the seal

and avoids exposing the weld to a peel force as discussed at page 7 of appellant's specification.

D. The Mascia et al. Reference Does not Overcome the Deficiencies of Beard et al. and Welter References

The rejection of claims 22, 24, 32 and 36 under 35 U.S.C. §103 as unpatentable over Beard et al. in view of Welter et al. as applied to claims 20 and 35, and further in view of Mascia et al. must also be reversed for the above reasons with respect to the Beard et al. and Welter references. The teachings of the Mascia et al. patent do not overcome the deficiencies of the Beard et al. and Welter et al. reference for the reasons previously discussed.

The Mascia et al. reference in no way overcomes the deficiency of the Beard et al. and Welter combination of references in that there is absolutely no suggestion of using ultrasound welding for sealing aerosol dispensers in Mascia. That is, Mascia does not teach one of ordinary skill in the art to use ultrasound to weld-seal aerosol containers, and the fact that the flanges in Mascia et al. may be rolled and crimped together does not render obvious the presently claimed invention requiring a metal to metal weld. As shown in the tables contained in the present specification, rolling and crimping together the materials without ultrasound welding is not equivalent to the presently claimed invention.

Accordingly, it is most respectfully requested that this rejection be reversed.

E. The Ryden Reference does not Overcome the Deficiencies of the Beard et al. Reference.

The rejection of claim 36 as unpatentable over Beard et al. in view of Ryden should also be reversed for the above reasons with respect to the Beard et al. reference. The Ryden reference in no way overcomes the deficiencies of the Beard et al reference. There is no suggestion of the metal to metal weld required by claim 20 which is incorporated into claim 36 which depends thereon. The Ryden

reference describes the administration of medicinal agents by inhalation from a container with a propellant. The container is described at line 47 of column 1 as a pressure tight container of metal or other material and the container is provided with a valve. The container is a separate unit from the dispenser and the Ryden invention relates to locking the dispenser to the container. There is no discussion of ultrasonically welding the closure to the body of the container or a container having such a closure and containing a medicament as required by claim 36 on appeal.

Accordingly, it is most respectfully requested that this rejection be reversed.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should not be sustained. The Final Rejection should be reversed and the application passed to issue.

Respectfully submitted,
BACON & THOMAS, PLLC

By: 
Richard E. Fichter
Registration No. 26,382

625 Slaters Lane - 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500

REF:ref
Appeal Brief.wpd

May 22, 2000

APPENDIX
CLAIMS ON APPEAL

20. An aerosol dispenser comprising a body, a closure sealed to the body, and means for dispensing material from the interior of the dispenser, wherein the closure is welded ultrasonically to the body by a metal-to-metal weld.
21. An aerosol dispenser according to claim 20, wherein the metal-to-metal weld is between annular flanges on the body and closure extending circumferentially about the axis of the body and closure.
22. An aerosol dispenser according to claim 21, wherein the flanges are outwardly directed and flat.
23. An aerosol dispenser according to claim 21 wherein the flanges are axially directed and cylindrical.
24. An aerosol dispenser according to claim 21 wherein the flanges are welded, rolled and crimped together.
25. An aerosol dispenser according to claim 21 wherein one of the flanges is of greater width than the other, and wherein the outer edge portion of the wider flange forms a U within which the outer edge portion of the narrower flange is located, both said edge portions extending generally parallel to the adjacent wall of the body.
26. An aerosol dispenser according to claim 20, which is an inhaler and contains an aerosol medicament.

27. A method of assembling an aerosol dispenser comprising a metal body, a metal closure, and means for dispensing material from the interior of the dispenser, wherein the closure is welded ultrasonically to the body by a metal-to-metal seal.

28. A method of assembling an aerosol dispenser according to claim 27, wherein the closure, which comprises an annular flange extending circumferentially about its axis, is positioned at the open end of and coaxially with the body, which comprises a complementary annular flange extending circumferentially about its axis, such that the flanges are parallel and in contact with each other.

29. A method of assembling an aerosol dispenser according to claim 27, wherein the flanges are welded together by means of an ultrasonic welding head which is brought into communication with the flanges and moved circumferentially along the flanges to create a substantially continuous weld between the flanges until a complete revolution about the axis of the closure and body has been performed.

30. A method of assembling an aerosol dispenser according to claim 28 wherein the flanges are outwardly directed and flat.

31. A method of assembling an aerosol dispenser according to claim 29, whereby the ultrasonic welding head causes relative vibration between the flanges in a direction which is radial with respect to the said axis.

32. A method of assembling an aerosol dispenser according to claim 27 wherein the flanges are bent to lie in a substantially axial direction after the flanges have been welded together.

33. A method of assembling an aerosol dispenser according to claim 28 wherein the said flanges are axially directed and cylindrical.

34. A method of assembling an aerosol dispenser according to claim 33 wherein the ultrasonic welding head causes relative vibration between the flanges in an axial direction.

35. A method of assembling an aerosol dispenser according to claim 27 wherein one of the said flanges is of greater width than the other and after the flanges have been welded together the wider flange is rolled and crimped around the other flange.

36. A method of assembling an aerosol dispenser according to claim 27 wherein the flanges are rolled and crimped after they have been welded together.